K081782

SEP 30 2008

Innocoll
Pharmaceuticals

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510(k) Summary

1. **Date Prepared:** June 13th , 2008

2. **Submitter** Innocoll Pharmaceuticals
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Submission Correspondent: Aaron Wyse
Director of Regulatory Affairs

3. **Proprietary Name:** Collieva™

4. **Common Name:** Topical Wound Dressing

5. **Device Classification:** Product Code: KGN
Classification Name: Dressing Wound Collagen
Regulatory Class: Unclassified

6. **Statement of Substantial Equivalence:**

Collieva™ is substantially equivalent in materials of construction and intended use to CollaGuard™ (K061746) manufactured by Syntacoll GmbH.

7. Intended Use

Collieva™ may be used for the management of wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- First and second degree burns
- Partial and full thickness wounds
- Superficial injuries

8. Description

Collieva™ is a clear collagen matrix film intended for topical use. The product is supplied sterile for single use only.

9. Biocompatibility

Collieva™ - biocompatibility testing has been completed against the requirements of ISO 10993 -1:2003. Collieva™ has been shown to be biocompatible as a topical wound dressing.

10. Conclusion

Collieva™ is substantially equivalent to the predicate device delineated in this submission and meets the requirements for premarket notification as defined in CFR21, Part 807.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2008

Innocoll Pharmaceuticals, Limited
Mr. Aaron Wyse
Director, of Quality and Regulatory Affairs
Midlands Research and Innovation Centre,
Dublin Road
Athlone, Colorado Westmeath
IRELAND

Re: K081782
Trade/Device Name: Collieva
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: KGN
Dated: June 13, 2008
Received: July 7, 2008

Dear Mr. Wyse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K081782

Device Name: Collieva

Indications For Use:

Indications:
Collieva may be used for the management of wounds such as:

- Pressure ulcers
- Venous stasis ulcers
- Diabetic ulcers
- First and second degree burns
- Partial and full thickness wounds
- Superficial injuries

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081782